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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/890,323	12/10/2001	Douglas P. Cerretti	2517-USA	9524

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IMMUNEX CORPORATION
LAW DEPARTMENT
51 UNIVERSITY STREET
SEATTLE, WA 98101

EXAMINER
MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)
09/890,323	CERRETTI, DOUGLAS P

Office Action Summary

Examiner	Art Unit
William W. Moore	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *1-3,7-12 and 14-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1☐ Certified copies of the priority documents have been received.

2☐ Certified copies of the priority documents have been received in Application No. _____.

3☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

16)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7 and 10.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group XXII, claims 4-6 and 13 drawn to a SVPH-1a polypeptide of SEQ ID NO:12 or a polypeptide which comprises SEQ ID NO:12, in Paper No. 9 filed April 4, 2002, is acknowledged. The traversal is on two grounds. The first is that at least the various SVPH-1 polypeptides – the SVPH-1a of the elected Group and the SVPH-1b and SVPH-1c polypeptides of Groups XXIII and XXIV – form a single general invention because they are linked by a common region of amino acid sequence identity, a domain. This argument is persuasive because sequence comparisons of SEQ IDs NOs:12-14 show that the carboxyl-terminal amino acid sequence regions of the SVPH-1b and SVPH-1c polypeptides, respectively SEQ IDs NOs:13 and 14, diverge only slightly from the corresponding region of SEQ ID NO:12. SEQ ID NO:13 is 99.2% identical to SEQ ID NO:12 and diverges at position 751 of the 766 amino acid sequence of SEQ ID NO:12 by lacking the five terminal amino acids and having non-identical amino acids at three other intervening positions. SEQ ID NO:14 is 99.4% identical to SEQ ID NO:12 and diverges at position 751 of the 766 amino acid sequence of SEQ ID NO:12 by having non-identical amino acids at five intervening positions between 751 and 766. The restriction requirement as between Groups XXII-XXIV is, therefore, rescinded.

The second ground of traversal is that the nucleic acids of Groups I-III that encode the SVPH-1a, SVPH-1b and SVPH-1c polypeptides, and the antibodies of Groups XXXV-XXXVII that may react with SVPH-1a, SVPH-1b and SVPH-1c polypeptides, form a single general invention with the SVPH-1a, SVPH-1b and SVPH-1c polypeptides themselves. Paper No. 9 argues that because the international examination considered the nucleic acids and the antibodies together with the SVPH-1a, SVPH-1b and SVPH-1c polypeptides, they

explain how these structurally different and chemically distinct compounds can share any special technical feature. Paper No. 9 presents no particular argument that addresses the restriction requirement as between an invention of Groups XXII-XXIV and an invention of the structurally divergent Groups XXIX-XXXI even though it suggests that these inventions may be rejoined. The requirement for restriction as between Groups XXII-XXIV and the Groups I-XXI and XXV-XXXI is still deemed proper and is therefore made FINAL. Claims 4-6 and 13 are examined herein to the extent that a SVPH-1a, a SVPH-1b or a SVPH-1c polypeptide is an integral polypeptide, or is comprised within a larger polypeptide, or comprises a domain described by claim 13.

Information Disclosure Statement

Applicant's information disclosure statement, Paper No. 7 filed January 23, 2002, is hereby acknowledged.

Preliminary Amendment

Applicant's Preliminary Amendment A, Paper No. 10 filed April 4, 2002, has been entered at page 1, line 1, of the specification, perfecting Applicant's claim to domestic priority.

Claim Rejections - 35 USC § 101

35 U.S.C. §101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4-6 and 13 are rejected under 35 U.S.C. §101 because the claimed invention lacks patentable utility.

A claimed invention must posses a specific, substantial and credible *in vitro* or *in vivo* utility. It is agreed that SEQ IDs NOs:12-14 encode metalloprotease products which arise by alternate splicing of a nuclear transcript and that the products share common protease and disintegrin domains. The specification states no specific *in vitro* utility for any isolated

for further research to determine, e.g., its specific biological role, thus identifying or confirming a "real world" context for its use, cannot be considered to be a "substantial utility". *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). The specification teaches, page 67, that mRNA transcripts encoding one or more of the SVPH-1a, SVPH-1b, or SVPH-1c metalloproteases can be detected in human testicular tissue. The specification suggests, page 17, that the isolated SVPH-1a, SVPH-1b, or SVPH-1c metalloproteases may be used to study "cell/cell and cell/matrix interactions involved in cellular processes", but is silent about the nature of any potential cellular process that requires the presence or activity of either the SVPH-1a, the SVPH-1b, or the SVPH-1c metalloprotease. The specification fails to indicate the nature of the activity of any of these three related products, whether it is exoproteolytic or endoproteolytic, whether it acts within a cell or acts outside a cell, and also fails to identify the nature of any substrate for these related products that might make the asserted utility of screening for inhibitors, page 7, meaningful. The specification's assertion that claimed product may be used as a molecular mass marker does not rise to the level of a specific utility - another polypeptide will serve this purpose - and no disclosure in the specification indicates that at the time the application was filed Applicant was aware of any specific utility for a SVPH-1a, SVPH-1b, or SVPH-1c metalloprotease that would permit its immediate use by the public.

The prior art made of record with Applicant's Information Disclosure shows that other structurally-related metalloproteases actively degrade extracellular matrix proteins such as collagen, fibronectin, and proteins of the *zona pellucida* surrounding mammalian ova, and further shows that other metalloproteases are able to degrade connective tissue protein substrates, allowing them to play key roles in tissue remodeling in development and disease in vertebrates and invertebrates, as well as regulating the homeostasis of various connective

venom of vipers are responsible for inducing circulatory system collapse in their prey. Applicant is invited to show that the specification indeed establishes a **specific** utility for at least one of the SVPH-1a, SVPH-1b, or SVPH-1c metalloproteases, and to show that this specific utility is substantial.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-6 and 13 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, since the claimed invention is not supported by either a **specific** asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

To the extent that claims 4-6 and 13 describe an integral SVPH-1a, SVPH-1b, or SVPH-1c polypeptide, one of these products comprised within a larger polypeptide, or polypeptide that comprises a domain recited by claim 13, they are free of the prior art made of record with Applicant's information disclosure. There is no disclosure the art before Applicant's priority date of a metalloprotease amino acid sequence for a claimed invention having any closer sequence relationship to SEQ IDs NOs:12-14 herein than the 48.7% identity the sequence of the ADAM 20 metalloprotease shares with SEQ ID NO:12. The amino acid sequence of the ADAM 20 metalloprotease disclosed in 1998 by Hooft van Huijsduijnen lacks any regions of contiguous sequence identity adequate to anticipate or render obvious any of the domains that claim 13 herein recites. The amino acid sequence of the SVPH1-8 metalloprotease disclosed in the WIPO publication WO

SEQ ID NO:12 herein and similarly lacks any regions of contiguous sequence identity adequate to anticipate or render obvious any of the domains recited in claim 13 herein. WO 99/36549 is not prior art because it was published after the domestic priority date established for the invention of Groups XXII-XXIV elected by Applicant. Because the elected invention presents no issues under the first paragraph of 35 U.S.C. §112 of enablement as to making or of inadequate written description, a response demonstrating that the specification indeed discloses a specific and substantial utility for the claimed subject matter and that amends claim 4 to make it an independent claim that defines the subject matter of the elected Groups XXII-XXIV, as well as canceling the non-elected claims, would permit allowance of claims describing the elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached between 7:00AM-5:30PM EST on Mondays and Wednesdays, between 7:00AM-1:30PM EST on Tuesdays and Thursdays, and between 8:30AM and 5:00PM EST on Fridays. **The examiner's direct FAX telephone number is 703.746.3169.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached at 703.308.3804. Further fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

William W. Moore
June 12, 2002

CHARLES L. PATTERSON, JR.
PRIMARY EXAMINER
GROUP 1800